

K110445

MAR 17 2011

510(k) Summary
(Per 21 CFR 807.92)

General Company Information:

Nextremity Solutions, LLC
Arthur A. Alfaro
President/CEO
167 Stone Hill Road
Colts Neck, NJ 07722
Phone: (732) 683-9304
Fax: (732) 683-9476

Date Prepared March 14, 2011

General Device Information

Product Name: FlexFusion™ Fixation implant

Classification: Smooth or threaded bone fixation fasteners,
Product code: HWC - Class II

Predicate Device

Arthrex, Inc. Arthrex Bio-Pin
(Marketed as Arthrex Trim-It™ Spin Pin)
[510(k) K050259]

Pioneer Surgical Technology StayFuse™ Fixation implant
[510(k) Number K990804]

NewDeal SA NEWDEAL K Wire
[501(k) K022599]

Memometal Technologies, Inc. Memometal Intramedullary Arthrodesis Device
[510(k) K070598]

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Description

The Nextremity Solutions 3.4mm FlexFusion™ Fixation implant system consists of a two-part 3.4mm diameter bone fixation implant. The proximal and distal components are provided as a set and as a procedure pack with the necessary surgical site preparation and insertion instruments. The Nextremity Solutions FlexFusion™ Fixation Implant is fabricated from medical grade stainless steel and the design allows the clinician to establish a natural angulation of the fused inter-digital joint.

Intended Use (Indications)

The Nextremity Solutions FlexFusion™ Fixation Implant is indicated for small bone reconstruction limited to inter-digital repair and fusion of the lesser toes.

Substantial Equivalence

The Nextremity Solutions FlexFusion™ Fixation implant possesses the same technologic characteristics of the predicate devices. These include the intended use, basic design, material, size and fundamental technology.

Performance Data

Mechanical testing was performed as described in relevant recognized standards, including testing for pull-out force, driving torque, torque to failure, static and dynamic flexion extension resistance. Results from cadaver test labs were also presented.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Nextremity Solutions, LLC
% Mr. Arthur A. Alfaro
President/CEO
167 Stone Hill Road
Colts Neck, New Jersey 07722

MAR 17 2011

Re: K110445

Trade/Device Name: FlexFusion Fixation Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 14, 2011
Received: February 16, 2011

Dear Mr. Alfaro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

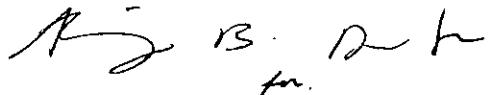
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110445

Device Name: Nextremity Solutions, FlexFusion™ Fixation implant

Indications For Use:

The Nextremity Solutions FlexFusion™ Fixation Implant is indicated for small bone reconstruction limited to inter-digital repair and fusion of the lesser toes.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson
Division Sign-Off
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Number

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